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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/730,161 | 12/08/2003 | Marco Serra | MDE-002C1 | 2317 |
| 42532 | 7590 | 07/12/2005 | EXAMINER | |
| PROSKAUER ROSE LLP ONE INTERNATIONAL PLACE 14TH FL BOSTON, MA 02110 | | | VO, HAI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1771 | |

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,161

Applicant(s)

SERRA ET AL.

Examiner

Hai Vo

Art Unit

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-57 is/are pending in the application.
4a) Of the above claim(s) 43-57 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 24-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1208.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election of Group I, claims 24-42 in the reply filed on 06/16/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24-34, and 37-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kabra et al (6,030,442). Kabra disclose a microporous gels made from N-isopropopylacrylamide gels which is exactly the same material being used by Applicants. The microporous gels has pore size ranging from 0.01 to 100 microns, which reads on Applicants' open cell foam (column 5, lines 60-65). Kabra discloses the hydrogel being capable of shrinking and swelling in response to change in temperature (column 7, lines 60-65).

The gel polymers are used to remove water from drilling mud. Likewise, the gel polymers are water permeable. Kabra does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that Kabra uses the same gel particles as Applicants, therefore, it is not seen that the microporous gel would have performed differently than the material of the present invention in term of expanding and contracting in response to the temperature of the fluid to which the gel particles are exposed. Kabra does not specifically disclose the microporous gel is used in a wet suit. It has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art microporous gel satisfying the claimed structural limitations.

Ex parte Masham, 2 USPQ2d 1647 (1987). Accordingly, it is the examiner's position that Kabra anticipates or strongly suggests the claimed subject matter.

5. Claims 24-31, 33-35, and 37-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asher et al (US 5,854,078). Asher disclose a sensor device comprising gel particles made from N-isopropopylacrylamide gels which is exactly the same material being used by Applicants. The gel contains N-butylacrylamide monomers (column 5, lines 32-33). Asher discloses the hydrogel being capable of shrinking and swelling in response to specific stimuli applied thereto (abstract). The device is soaked in the water for lead

detection (column 7, lines 15-30). The device should be water permeable for successful operation. Asher does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that Asher uses the same gel particles as Applicants, therefore, it is not seen that the sensor device would have performed differently than the material of the present invention in term of expanding and contracting in response to the temperature of the fluid to which the gel particles are exposed. Asher does not specifically disclose the device is used in a wet suit. It has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art sensor device satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Accordingly, it is the examiner's position that Asher anticipates or strongly suggests the claimed subject matter.

6. Claims 24-34, and 37-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bashan (US 3,900,030).

Bashan discloses a tampon comprising an open cell foam matrix containing hydrogel particles (abstract). The tampon is made from hydrophilic open celled polyurethane foam. Likewise, it is water permeable. Bashan does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the

temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that Bashan uses the open cell foam containing hydrogel particles as Applicants, therefore, it is not seen that the tampon would have performed differently than the material of the present invention in term of expanding and contracting in response to the temperature of the fluid to which the gel particles are exposed. Asher does not specifically disclose the device is used in a wet suit. It has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art tampon satisfying the claimed structural limitations.

Ex parte Masham, 2 USPQ2d 1647 (1987). Accordingly, it is the examiner's position that Bashan anticipates or strongly suggests the claimed subject matter.

7. Claims 24-34, and 37-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 301 753 (EP'753). EP'753 discloses a wound dressing comprising an open cell foam matrix containing hydrogel particles (abstract). The wound dressing contains water-absorbing materials, therefore it is water-permeable. EP'753 does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that EP'753 uses the open cell foam containing hydrogel particles as Applicants, therefore, it is not seen that the tampon would have performed differently than the

Art Unit: 1771

material of the present invention in term of expanding and contracting in response to the temperature of the fluid to which the gel particles are exposed. EP'753 does not specifically disclose the device is used in a wet suit. It has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art tampon satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Accordingly, it is the examiner's position that EP'753 anticipates or strongly suggests the claimed subject matter.

8. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kabra et al (6,030,442) in view of Asher et al (US 5,854,078). Kabra discloses the microporous gel for used in sensors comprise N-alkylacrylamide monomers. Kabra does not specifically disclose N-butylacrylamide monomers. Asher, however, discloses a sensor device comprising gel particles made from N-butylacrylamide monomers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add N-tert-butylacrylamide monomer to the microporous gel motivated by the desire to change the sensitivity of the gel by making the hydrogel more hydrophobic or hydrophilic as desired by the needs of the user.
9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bashan (US 3,900,030) or EP 0 301 753 as applied to claim 24 above, in view of Itoh et al (US 4,828,710). Neither Bashan nor EP'753 discloses the hydrogel made from N-tert-butylacrylamide. Itoh, however, discloses raw materials for macromolecular

Art Unit: 1771

absorbents suitable for use in as sanitary napkins and diapers comprising N-tert-butylacrylamide monomers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the hydrogel made from N-tert-butylacrylamide monomers because such is an intended use of the material and Itoh provides necessary details to practice the invention of Bashan/EP'753.

10. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bashan (US 3,900,030) as applied to claim 24 above, and further in view of Zadini et al (US 5,609,586). Bashan does not specifically disclose the catamenial tampon comprising a neoprene layer. Zadini, however, discloses a catamenial device comprising a tampon 104 and an expandable member 105 made from neoprene. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catamenial tampon having an expandable neoprene layer motivated by the desire to provide sealable closure of vaginal canal.
11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 301 753 as applied to claim 24 above, and further in view of Peterson (US 5,538,500). EP'753 does not specifically disclose the wound dressing comprising a neoprene layer. Peterson, however, discloses a medical dressing including an absorbent pad and an elastic bandage wrap made from neoprene to secure the dressing to the wearer. The elasticity of the bandage wrap enhances the patient's comfort when the dressing is worn. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wound dressing comprising

Art Unit: 1771

an elastic neoprene bandage wrap motivated by the desire to enhance the patient's comfort when the dressing is worn.

Information Disclosure Statement

12. The references cited by the examiner Nihir Patel in the Application No. 09/840,836 are not considered because they fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (2) a heading that clearly indicates that the list is an information disclosure statement. The PTO-892 forms have been placed in the application file, but the information referred to therein has not been considered. Applicants are requested to resubmit the compliant IDS in next response for consideration.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on M,T,Th, F, 7:00-4:30 and on alternating Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HV

Hai Vo

HAI VO
PRIMARY EXAMINER